

REMARKS

Claims 40, 43, 44, 48 and 50-56 were acted upon in the aforesaid Office Action. New Claims 57-64 have been added and claims 1-39, 41, 42, 45-47, 49 and 52-55 have been canceled, leaving claims 40, 43, 44, 48, 50, 51 and 56-64 for consideration.

Amendments explained

Claims 40 and 48 have been amended to remove reference to the trademark and trade name. The amended claims 40 and 48 refer to an FDM system. Further, claims 40 and 48 have been amended to clarify that the lay-down patterns form triangular and five-sided polygonal pores, respectively. New claims 57 to 64 have been added. Basis for the amendments are found at least at page 48, line 19 to page 49, line 2 of the application as originally filed; page 40, lines 16 to 18; page 41, lines 5 to 6; and page 41 line 20 to page 42, line 3.

Claims 52 to 55 have been canceled.

Rejection under 35 USC §112, first paragraph

The Examiner at page 3, section 8 of the Office Action has rejected claims 40, 43, 44, 48 and 50-56 as failing to comply with the written description requirements. In particular, the Examiner is of the opinion that the claims are drawn to a genus and that the description does not provide adequate written description of the claimed genus, i.e. a three-dimensional

apparatus having lay-down patterns forming triangular or five-sided polygonal pores. The Examiner also states that the person skilled in the art would recognize that the applicant was not in possession of the genus. This objection is respectfully traversed.

As claims 52 to 55 have been deleted, the rejection in respect of claims 52 to 55 is rendered moot.

MPEP §2163 provides that when a disclosure describes a claimed invention in a manner that permits one skilled in the art to reasonably conclude that the applicant possessed the claimed invention, the written description requirement is satisfied. The possession may be shown in any number of ways and an applicant need not describe every claim feature exactly because there is no requirement to do so according to MPEP §2163. It is provided that in order to satisfy the written description requirement, it must be shown with "reasonable clarity" (MPEP § 2163.02) that the applicant was in possession of the invention.

The applicant submits that one of ordinary skill in the art would reasonably conclude that the applicant's disclosure adequately described the claimed invention at the time of filing the application at least because the feature of the apparatus of claims 40 and 48 is taught by the present application as originally filed at least at pages 33 to 43. The applicant also described and illustrated the apparatus in Example 1 (page 48 to 54 of the application as originally filed) and at Figures 3A, 3B, 4A and 4B. From the disclosure, the applicant submits that the person of ordinary skill in the art would have understood

that the apparatus of claims 40 and 48 could be used in tissue engineering having a lay-down pattern forming triangular and five-sided polygonal pores.

The MPEP further provides at §2163(II)(3)(a)(ii) that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. As explained above, the applicant submits that the application as originally filed adequately discloses an apparatus for use in tissue engineering having lay-down patterns forming triangular and five-sided polygonal pores, as claimed in claims 40 and 48, respectively.

In view of the above, the applicant submits that it can be reasonably concluded that the applicant possessed the claimed apparatus. Therefore, the present application adequately describes the claimed invention.

#### **Rejection under 35 USC §102**

The Examiner at page 5, section 10 of the Office Action has rejected claims 40, 43, 44, 48 and 50-56 as being anticipated by Cima et al ("Cima"). The Examiner has acknowledged that the lay-down pattern of "triangles" and "five-sided polygon" does not appear in Cima.

Without conceding to the Examiner, but only for the purposes of expediting the prosecution of the present application, claims 52 to 55 have been deleted. Accordingly, the

applicant submits that there should be no confusion on the criticality of the scaffold lay-down pattern, and that claims 40 and 48, and their dependent claims, are not anticipated by Cima.

**Rejection under 35 USC §112, second paragraph**

At page 6, sections 12 to 14 of the Office Action, the Examiner has rejected claims 40, 43, 44, 45, 48 and 50-56 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40 and 48 have been amended to remove reference to the trademark "STRATASYS, INC" and trade name "FDM 3D MODELER". Accordingly, the applicant submits that the objection to claims 40, 43, 44, 45, 48 and 50-56 is rendered moot.

Without conceding to the Examiner, but only for the purposes of expediting the prosecution of the present application, claims 52 to 55 have been deleted. Accordingly, the applicant submits that the objection in respect of claims 52 to 55 as highlighted at sections 13 and 14 of the Office Action is rendered moot.

**Rejection under 35 USC §103**

**A. Cima**

The Examiner at section 19 at page 8 of the Office Action has rejected claims 40, 43, 44, 45, 48 and 50-56 as being

unpatentable over Cima. The applicant disagrees with the Examiner's comments. As claims 52 to 55 have been deleted, the rejection in respect of claims 52 to 55 is rendered moot.

The Examiner states that Cima teaches that the patterns can be varied, depending on the design and structural needs of the maker. Further, the Examiner states that the variations in the lay-down patterns would have been predictable to one skilled in the art. However, as acknowledged by the Examiner, Cima does not disclose, nor suggest, the specific lay-down patterns as that recited in claims 40 and 48. Although it has been suggested that different lay-down patterns can be manipulated by varying the printing instructions, given the lack of suggestion of a lay-down pattern forming triangular or five-sided polygonal pores in Cima, there would be an undue burden of experimentation on the person of ordinary Skill in the art to arrive at the claimed lay-down pattern of forming triangular and five-sided polygonal pores.

Further, the advantages conferred and unexpected results obtained by a lay-down pattern which forms triangular and five-sided polygonal pores, as provided at page 41, line 9 to page 42, line 13 of the application as originally filed, would not have been obvious to a person of ordinary skill in the art referring to Cima since there has been no suggestion in Cima how such advantages can be achieved. Even if the person of ordinary skill in the art referred to Cima, the person would understand from the teachings of Cima that the 3DP method is preferred over other solid free-form methods, such as FDM.

Accordingly, there is no prima facie case of obviousness in respect of claims 40 and 48, and their dependent claims, as all the features of the claimed invention cannot be derived from the teachings of Cima.

B. Richter et al (US Patent No. 6,280,478) in view of Cima

The Examiner at page 10, section 20 of the Office Action has rejected claims 40, 43, 44, 45, 48 and 50-56 as being unpatentable over Richter et al ("Richter") in view of Cima. The applicant disagrees with the Examiner's comments. As claims 52 to 55 have been deleted, the rejection in respect of claims 52 to 55 is rendered moot.

In addition to the arguments provided above in respect of Cima, which apply equally to this section, and as acknowledged by the Examiner at paragraph (c) at page 11 of the Office Action, there is no disclosure or suggestion in either Richter or Cima of the specific lay-down patterns forming triangular or five-sided polygonal pores, as recited in claims 40 and 48, respectively. Although the Examiner is of the opinion that the person of ordinary skill in the art would have predicted the lay-down pattern of forming triangular or five-sided polygonal pores as recited in claims 40 and 48 in view of design incentives or other market forces, no evidence of such design incentives or other market forces has been provided to show that the person of ordinary skill in the art would have motivated to arrive at the claimed lay-down patterns.

It would also not have been obvious to a person of ordinary skill in the art referring to Richter in view of Cima that the apparatus of claims 40 and 48 provides the advantages and unexpected results as described at page 41, line 9 to page 42, line 13 of the application as originally filed.

Further, it is known that almost all inventions, patentable or not, are founded upon market forces or design incentives. Most device or apparatus inventors start from a premise of improving the design of some current apparatus, and/or responding to market pressure, or desires, to have an improved device. This ground for rejection is believed to be inappropriate. It would appear that the test should be whether the invention set forth in claims 40 and 48 is novel, useful and unobvious. As explained above, the apparatus as recited in claims 40 and 48 is new and useful; and inasmuch as no prior art shows or suggests the device as set forth in claim 40 and 48, the applicant submits that claims 40 and 48 appear not to be obvious with respect to the teachings of Richter and Cima,

Accordingly, there is no motivation for the person of ordinary skill in the art to arrive at the lay-down pattern as recited in claims 40 and 48. Given the lack of suggestion in Richter and Cima, an undue burden of experimentation would be posed on the person of ordinary skill in the art in deriving at the specific lay-down pattern as recited in claims 40 and 48.

In view of the above, the applicant submits that there is no prima fade case of obviousness in respect of claims 40 and 48, and their dependent claims, as all the features of the

claimed invention cannot be derived from the teachings of Richter in view of Cima.

In view of the above, allowance of claims 40, 43, 44, 48, 50, 51, and 56-64 appear to be in order and is most respectfully requested.

In the event that any fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Scott R. Foster".

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